



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 6/27/18

Subject: Efficacy Review for SS Triple S Navigator #6 SynerSys Sporicidal Disinfectant,
EPA Reg. No. 12120-4 DP Barcode: 446474, E-Submission: N/A

From: Samantha Collins
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Thru: Kristen Willis, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P) *Kristen Willis*

To: Zeno Bain / Terria Northern
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Standardized Sanitation Systems, Inc..
2 Executive Park Dr.
Billerica, MA 01862

Formulation from the Label:

Active Ingredient(s)	% by wt.
Peroxyacetic Acid	5.9%
Hydrogen Peroxide	27.3%
Other Ingredients	66.8%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): hospital and healthcare disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal, sporicidal) and food contact surface sanitizer for use on hard, non-porous surfaces

Requested action(s): Confirmatory data submitted due to addition of fragrance to dilution. Additional organisms added and confirmatory data for contact time change.

Documents considered in this review:

- Letter from applicant to EPA dated March 2, 2018
- Data Matrix (EPA Form 8570-35)
- 5 efficacy studies (MRID 50544203-50544207)
- 2 supplemental efficacy discussions (MRID 50544201-50544202)
- Proposed label dated 11/06/2015
- Confidential Statement of Formula (EPA Form 8670-4) Reg. No. 12120-4 dated 09/29/14. NOTE: No updated CSF was submitted to reflect the change in addition of fragrance.
- Confidential Statement of Formula (EPA Form 8670-4) Reg No. [REDACTED]

II PROPOSED DIRECTIONS FOR USE

**“FOR USE AS A {ONE-STEP} {GENERAL}{HOSPITAL}{MEDICAL} DISINFECTANT
{VIRUCIDE}{FUNGICIDE}{CLEANER}:**

1. Pre-clean heavily soiled areas.
2. Apply use solution of (insert appropriate hospital/health care/medical/non-medical dilution here) to disinfect hard, non-porous surfaces with a sponge, brush cloth, mop, {by immersion}, {auto scrubber}, {{mechanical spray devise}, {{{hand pump} {course}}} trigger spray device.} For spray applications, spray 6-8 inches from surface. Do not breath spray}.
3. Treated surfaces must remain wet for (insert appropriate hospital/health care/medical/non-medical contact time here).
4. [{Wipe dry} {with clean cloth {or} {allow to air dry}}]. {Rinsing of floors is not necessary unless they are to be waved or polished.}
5. Prepare a fresh solution daily of when visibly dirty.

Product ingredient source information may be entitled to confidential treatment

III STUDY SUMMARIES

1.	MRID	50544203	Study Completion Date:	06/07/2016			
Study Objective		Disinfectant					
Testing Lab; Lab Study ID		Accuratus, A20887					
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708) and Pseudomonas aeruginosa (ATCC 15422)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SSS Triple 8 Navigator #63 SynerSys Sporidical Disinfectant Cleaner Part A and SSS Triple S Navigator #63 SynerSys Fragrance Additive Part B					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Part A Lot# 50508Z4 and Lot# 51012Z1 Part B Lot# 070316A and Lot# 0703168					
	Preparation	<p>Tested concentration: > nominal</p> <p>Dilution: Lot# 50508Z4 (Part A) with Lot# 070316A (Part B) 1:32 defined as 0.927 mL (Part A) + 1.0 mL (Part B) + 30.073 mL of diluent.</p> <p>Lot# 51012Z1 (Part A) with Lot# 070316B (Part B) 1:32 defined as 0.962 mL (Part A) + 1.0 mL (Part B) + 30.038 mL of diluent</p> <p>Diluent: 400 ppm AOAC Synthetic Hard Water</p>					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10 per batch					
Test conditions		Contact time	1 min 55 sec	Temp	20°C	RH	N/A
Neutralizer		Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate + 0.01% Catalase					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)							

2.	MRID	50544204	Study Completion Date:	02/21/2017
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus, A22521		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Shigella dysenteriae (ATCC 11835)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	Name/ID	SSS Triple 8 Navigator #63 SynerSys Sporocidal Disinfectant Cleaner Part A		
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	61003Z1		
	Preparation	Tested concentration: > nominal Dilution: 0.96 mL of test substance + 31.04 mL of diluent Diluent: 400 ppm AOAC Synthetic Hard Water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 10 per batch		
Test conditions		Contact time	1 min 55 sec	Temp 20°C RH N/A
Neutralizer		Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate + 0.01% Catalase		
Reviewer comments (i.e. protocol deviations)				

3.	MRID	50544205	Study Completion Date:	05/31/2016
Study Objective		Disinfectant		
Testing Lab; Lab Study ID		Accuratus, A20890		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Shigella dysenteriae (ATCC 11835)		
Test Method		AOAC Use Dilution Method		
Application Method		Liquid		
Test Substance Preparation	Name/ID	SSS Triple 8 Navigator #63 SynerSys Sporocidal Disinfectant Cleaner Part A		
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	50508Z4 and 51012Z1		
	Preparation	Tested concentration: > nominal Dilution: 1:32 ≈ 0.96 mL of test substance + 31.0 mL of diluent Diluent: 400 ppm AOAC Synthetic Hard Water		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Stainless steel penicylinders, 10 per batch		
Test conditions		Contact time	2 min	Temp 20°C RH N/A
Neutralizer		Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate + 0.01% Catalase		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The dilution of lot 51012Z1 did not result in an acceptable concentration, as the active ingredient value was above nominal. Therefore, a new study (A22521) was completed using lot 61003Z1. The dilution in this study resulted in a valid concentration of active ingredient. Together the two studies represent a valid assessment of the product's performance against this organism. (per mrid 50544202 efficacy discussion)		

4.	MRID	50544206	Study Completion Date:	05/31/16			
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A20851					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		2009-H1N1 Influenza A virus (Novel MINI), Strain A/Mexico/4108/2009, CDC #2009712192					
Indicator Cell Culture		MDCK (canine kidney) cells (ATCC CCL-34)					
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SSS Triple S Navigator #63 SynerSys Sporocidal Disinfectant Cleaner Part A					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	50508Z4 and 51012Z1					
	Preparation	Tested concentration: 1:32, > nominal ≈15.0 mL of test substance diluted to 500 mL 400 ppm AOAC Synthetic Hard Water					
Soil load		5% FBS					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		Contact time	2 min	Temp	20.0°C	RH	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)		Change in contact time.					

5.	MRID	50544207	Study Completion Date:	01/31/17			
Study Objective		Disinfectant – virucidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A22385					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Duck Hepatitis B virus as a surrogate for human Hepatitis B virus					
Indicator Cell Culture		Hepatocytes					
Test Method		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SSS Triple S Navigator #63 SynerSys Sporocidal Disinfectant Cleaner Part A					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	61003Z1					
	Preparation	Tested concentration: 1:32, > nominal 0.96 mL of test substance + 31.04 mL of 400 ppm AOAC Synthetic Hard Water					
Soil load		5% FBS and 100% whole duck serum					
Carrier type, # per lot		1 glass petri dish carrier per batch					
Test conditions		Contact time	1 min 55 sec	Temp	20.0°C	RH	--
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)		Change in contact time.					

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Average log ₁₀ CFU/Carrier
		Batch 50508Z4 Batch 070316A	Batch 51012Z1 Batch 0703168	
1 minute 55 second contact time, 400 ppm synthetic hard water, 5% soil load,				1:32 dilution
50544203	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/10	0/10	6.65
	<i>Salmonella enterica</i> (ATCC 10708)	0/10	0/10	5.52
	<i>Staphylococcus Aureus</i> (ATCC 6538)	0/10	0/10	6.27
MRID	Organism	Batch 61003Z1		Average log ₁₀ CFU/Carrier
50544204	<i>Shigella dysenteriae</i> (ATCC 11835)	0/10		4.71
MRID	Organism	Batch 50508Z4	Batch 51012Z1	Average log ₁₀ CFU/Carrier
2-minute contact time, 400 ppm synthetic hard water, 5% soil load, 1:32 dilution				
50544205	<i>Shigella dysenteriae</i> (ATCC 11835)	0/10	0/10	5.11

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			Batch 50508Z4	Batch 51012Z1	
2-minute contact time, 400 ppm synthetic hard water, 5% soil load, 1:32 dilution					
50544206	2009-H1N1 Influenza A virus (Novel MINI), Strain A/Mexico/4108/2009, CDC #2009712192)	10 ⁻¹ to 10 ⁻⁸ dilution	Complete inactivation	Complete inactivation	6.00
		Log ₁₀ TCID ₅₀ /carrier	≤0.50	≤0.50	
		Log Reduction	≥5.50	≥5.50	
MRID	Organism	Description	Batch 50508Z4		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
1-minute 55-second contact time, 400 ppm synthetic hard water, 5% FBS and 100% whole duck serum soil load, 1:32 dilution					
50544207	Duck Hepatitis B virus as a surrogate for human Hepatitis B virus	10 ⁻¹ to 10 ⁻⁴ dilution	Complete inactivation		Replicate #1: 7.25
		Log ₁₀ TCID ₅₀ /carrier	≤0.50		Replicate #2: 5.75
		Log Reduction	≥6.35		

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50544203	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 1:32 defined as ≈0.9 mL (Part A) + 1.0 mL (Part B) + ≈30.0 mL of diluent (400 ppm AOAC Synthetic Hard Water)	1 min 55 sec	5%	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • <i>Pseudomonas aeruginosa</i> (ATCC 15442) • <i>Staphylococcus aureus</i> (ATCC 6538) • <i>Salmonella enterica</i> (ATCC 10708) 	No
50544204	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, 1:32 defined as 0.96 mL of test substance + 31.04 mL of diluent (400 ppm AOAC Synthetic Hard Water)	1 min 55 sec	5%	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • <i>Shigella dysenteriae</i> (ATCC 11635) 	No

50544205	Disinfectant, bactericidal	Hard, non-porous surfaces	1:32 defined as ≈0.9 mL of test substance + ≈31.0 mL of diluent (400 ppm AOAC Synthetic Hard Water)	2 min	5%	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • <i>Shigella dysenteriae</i> (ATGG 11835) 	
50544206	Disinfectant, virucidal	Hard, non-porous surfaces	1:32 defined as ≈15.0 mL of test substance diluted to 500 mL	2 min	5%	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • 2009-H1N1 Influenza A virus (Novel MINI), StrainA/Mexico/4108/2009, CDC #2009712192 	No
50544207	Disinfectant, virucidal	Hard, non-porous surfaces	1:32 defined as 0.96 mL of test substance + 31.04 mL of 400 ppm AOAC Synthetic Hard Water	1 min 55 sec	5% FBS and 100% whole duck serum	400 ppm AOAC Synthetic Hard Water	<ul style="list-style-type: none"> • Duck Hepatitis B virus as a surrogate for human Hepatitis B virus 	No

VI LABEL COMMENTS

Label Date:02/07/2018

1. The proposed label claims that the product, SS Triple S Navigator #6 SynerSys Sporocidal Disinfectant, EPA Reg. No. 12120-4, when diluted at a ratio of 1:32 of product per 400 ppm AOAC Synthetic Hard Water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Shigella dysenteriae (ATCC 11635)

2009-H1N1 Influenza A virus (Novel MINI), Strain A/Mexico/4108/2009, CDC #2009712192

Duck Hepatitis B virus as a surrogate for human Hepatitis B virus

These claims are **not acceptable** as they are not supported by the submitted data. All of the product lots used in testing have active ingredient concentrations above the nominal value. Base claims against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), and *Salmonella enterica* (ATCC 10708) should be tested at the Lower Certified Limit (LCL), any additional organisms should be tested at the nominal value or below. Additionally, for the confirmatory data, the product was diluted to the ratio 1:32 which is not the most dilute concentration listed on the label at a 2-minute contact time. The data does not support use of the additional fragrance formulation since the confirmatory data does not support the claims proposed.

- No public health claims can be made for the formulation with additional fragrance.
- The existing public health claims associated with the current registration may be maintained as they exist on the most recently approved label (accepted date January 15, 2015) with the CSF dated 09/29/2014.
- No new changes to the label 09/29/2014 have been reviewed or approved by the efficacy team at this time.